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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VANDA PHARMACEUTICALS INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 23- ____ *Document Electronically Filed* **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Vanda Pharmaceuticals Inc. (Vanda) for its complaint against Defendant Teva Pharmaceuticals USA, Inc. (Teva) alleges as follows:

NATURE OF THE ACTION

1. This is an action to enjoin and to recover damages as a result of Teva's false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

2. Vanda is a small, innovative pharmaceutical company whose business model largely consists of acquiring compounds that other companies failed to develop into a useful treatment, identifying potential medical uses for them, devoting substantial resources to developing them, seeking FDA approval, and commercializing them.

3. One of its drugs is HETLIOZ® (tasimelteon), a circadian-rhythm regulator, that is the first and only FDA-approved therapy to treat two rare disorders—Non-24-Hour Sleep-Wake Disorder (Non-24) and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older.

4. In December 2022, Teva, a generic drug manufacturer, received final FDA approval to market a generic version of HETLIOZ®—but Teva intentionally sought approval only for a single indication (Non-24).

5. Nonetheless, immediately following the at-risk launch of its generic version of HETLIOZ®, Teva began publishing materially false and misleading marketing material that advertises and promotes its generic tasimelteon for uses beyond the narrow labeling that Teva sought and FDA approved. Some material even advertises uses of tasimelteon that FDA has *never* approved, even for HETLIOZ®.

6. Teva is thus deceiving patients, physicians, drug wholesalers, distributors, direct purchasers, insurance companies, HMOs, prescription drug plan sponsors, pharmacists, and pharmacies, into believing that its generic product is a safe and effective therapy to treat nighttime sleep disturbances SMS when it is not FDA-approved as such, and promoting its generic product as a hypnotic and/or sedative when FDA has not approved it as such.

7. This action therefore seeks to enjoin Teva from engaging in this false and misleading advertising to protect consumers from Teva's deception, to stop further irreparable harm to Vanda's reputation and goodwill, and to recover the substantial money damages that Vanda has suffered as a result of Teva's conduct and will continue to suffer should Teva not be enjoined.

THE PARTIES

8. Plaintiff Vanda is a pharmaceutical company with its principal place of business at 2200 Pennsylvania Ave. NW, Suite 300E, Washington, DC, 20037, and Vanda is incorporated in Delaware.

9. Teva is a pharmaceutical company that maintains its principal place of business at 400 Interpace Parkway, #3, Parsippany, NJ 07054, and Teva is incorporated in Delaware.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 15 U.S.C. § 1121 and 28 U.S.C. § 1331.

11. This Court has personal jurisdiction over Teva because Teva regularly conducts business in the District of New Jersey and its principal place of business is located in this district.

12. On information and belief, Teva designed, coordinated, reviewed, and/or published the false and misleading statements at issue from within this district.

13. Venue is appropriate in this district under 28 U.S.C. § 1391(b)(1) because Teva resides in the district and under 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this district.

BACKGROUND

A. Vanda and HETLIOZ®

14. Vanda is a small pharmaceutical company whose business model largely consists of acquiring compounds that other companies failed to develop into a useful treatment, identifying potential medical uses for them, devoting substantial resources to developing them, seeking FDA approval, and commercializing them.

15. Through this model, Vanda develops and markets innovative pharmaceutical products to address high-impact unmet patient needs. One of its drugs is HETLIOZ® (tasimelteon), a circadian-rhythm regulator.

16. Vanda acquired tasimelteon, now marketed as HETLIOZ®, from a large pharmaceutical company that tried, but failed, to develop it into a useful, FDA-approvable therapy.

17. HETLIOZ® is among a class of drugs known as melatonin receptor agonists, which bind to and activate receptors in the brain for melatonin, a hormone that regulates the sleep cycle.

18. Under Vanda's stewardship, and after devoting years and many millions of dollars to research, development, and regulatory processes, HETLIOZ® became the first and only FDA-approved therapy to treat two rare and orphan disorders: Non-24-Hour-Sleep-Wake Disorder (Non-24) and later nighttime sleep disturbances in Smith-Magenis Syndrome in patients 16 years or older.

19. Specifically, Vanda holds approved New Drug Application (NDA) No. 205677 for HETLIOZ® (tasimelteon) capsules, 20 mg, approved by the United States Food & Drug Administration (FDA) on January 31, 2014, for the treatment of Non-24.

20. Non-24 is a circadian rhythm disorder in which a patient's internal clock is mismatched to the 24-hour day/night cycle.

21. Individuals with Non-24 are unable to reset their circadian rhythm in response to daily environmental cues (like morning light), resulting in a shifting sleep/wake cycle that is untethered from the 24-hour day/night cycle.

22. During the intervals in which an individual's body is misaligned from the day/night cycle, that individual can experience insomnia and excessive daytime sleepiness.

23. Individuals with Non-24 also accumulate symptoms of chromic sleep deprivation, resulting in fatigue, depression, difficulty concentrating, and memory problems.

24. The FDA has recognized that Non-24 can be debilitating for many patients.

25. Non-24 is often associated with psychiatric disorders, including depression and bipolar disorder.

26. HETLIOZ® was approved for Non-24 patients following priority review and received orphan-product designation from the FDA because Non-24 is a rare disease or condition.

27. Many, but not all, individuals who suffer from Non-24 also suffer from blindness.

28. FDA has observed that "Non-24 is most prevalent in patients who are totally blind. It is estimated that *over half of totally blind individuals suffer from Non-24* and that approximately 100,000 people in the United States have the disorder." Exhibit 1 (FDA Non-24 Letter) at 2-3 (emphasis added).

29. On December 1, 2020, the FDA approved Vanda's supplemental New Drug Application (sNDA) 205677/S-007 allowing the marketing of HETLIOZ® to treat nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older.

30. SMS is a rare genetic disorder, a defining feature of which is an "inverted" circadian rhythm.

31. SMS sufferers generally have an onset of melatonin around 6:00 AM, reach peak sleepiness around 12:00 PM, and have a melatonin offset around 8:00 PM—approximately the opposite of a normal sleep pattern.

32. This inverted circadian rhythm makes it extremely difficult for patients with SMS to fall asleep and to stay asleep during the night and to stay awake during the day.

33. SMS patients also present with other physical, neurological, and behavioral symptoms, which the disorder's sleep disruptions can exacerbate.

34. If not successfully treated, SMS can cause significant disruption in the lives of patients and their families as well as contribute to health system costs.

35. HETLIOZ® was approved to treat nighttime sleep disturbances in SMS patients following priority review and received orphan-product designation from the FDA because SMS is a rare disease or condition.

36. Vanda's currently approved HETLIOZ® label notes that HETLIOZ® is "indicated for the treatment of" both "Non-24-Hour Sleep-Wake Disorder (Non-24) in adults" and "Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age or older."

37. The HETLIOZ® label further provides dosage and administration information for both Non-24 and nighttime sleep disturbances in SMS.

38. Vanda is also studying HETLIOZ® to treat additional conditions, including Jet Lag Disorder and Insomnia. Vanda has completed substantial studies to demonstrate HETLIOZ®'s safety and efficacy in treating these conditions. Vanda has submitted sNDAs to the FDA seeking to expand its approval to cover these additional indications.

39. Vanda is the owner of all rights, title, and interest in several patents that grant it various exclusive rights with respect to the making, using, offering for sale, and selling of tasimelteon and in the method for using and process for making tasimelteon, including patents relating to the use of tasimelteon to treat SMS patients.

40. Vanda has devoted millions of dollars and many years into the research, development, and regulatory approval of HETLIOZ®.

41. As demonstrated by its innovative Braille labeling and orphan drug designations, HETLIOZ®—the result of Vanda's work and innovation—improves quality of life and safety for a vulnerable population.

42. Vanda's commitment to improving quality of life and safety for vulnerable populations has engendered substantial goodwill toward Vanda among HETLIOZ® patients.

43. Vanda depends on the revenue from its products to continue its innovative research and development efforts, including:

a. HETLIOZ® as a treatment for insomnia, jet-lag disorder, delayed sleep-phase disorder, and sleep disturbances in patients with autism spectrum disorder.

b. FANAPT® (iloperidone) as a treatment for bipolar disorder and for Parkinson's disease psychosis, as well as developing a long-acting injectable formulation of iloperidone.

c. A third drug, tradipitant, as a treatment for gastroparesis, motion sickness, atopic dermatitis, and COVID-19 pneumonia.

d. Four early-stage compounds: one for treatment of several cancers; one as a treatment for dry eye and ocular inflammation; one as a treatment secretory diarrhea disorder; and one as a treatment for psychiatric disorders.

44. Vanda devotes a substantial portion of the revenue from its drugs, including HETLIOZ® to funding the development of new and innovative treatments. In the first 9 months of 2022, for example, Vanda reinvested approximately 90% of its total revenue into research and development and company operations, as reflected in its public filings.

B. Regulatory background

1. New drug applications

45. Under the Federal Food, Drug and Cosmetic Act (FDCA), to obtain marketing approval for a new drug, a drug sponsor must submit a New Drug Application to the FDA. *See* 21 U.S.C. § 355. And the drug sponsor must demonstrate by "substantial evidence," based on the sponsor's clinical trials and other supportive evidence, that the drug is safe and effective for its intended use. *Id.* § 355(d).

46. The pharmaceutical research and development process is both lengthy and expensive. Estimates suggest that it typically takes $2.6 billion and "at least ten years for a new medicine to complete the journey from initial discovery to the marketplace." Biopharmaceutical Research & Development: The Process Behind New Medicines, PhRMA at 1 (2015), perma.cc/PL5Y-YW7P.

47. Drug development generally involves three phases. *See* 21 C.F.R. § 312.21.

48. Phase I involves the initial introduction of a new drug into human subjects; it may be conducted in patients or healthy volunteer subjects; and it is "designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." 21 C.F.R. § 312.21(a)(1).

49. Phase II studies are "typically well controlled, closely monitored, and conducted in a relatively small number of patients" and are used to evaluate "effectiveness of the drug for a particular indication … and to determine the common short-term side effects and risks associated with the drug." 21 C.F.R. § 312.21(b).

50. Phase III studies are expanded trials, designed to "gather … additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling." 21 C.F.R. § 312.21(c).

51. These clinical trials make up a substantial portion of the time and expense that goes into development of a marketable drug.

52. Consistent with the U.S. Constitution's direction to Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries" (U.S. Const. art. I, § 8, cl. 8), the FDCA also provides a mechanism for drug sponsors to protect their patent rights.

53. As part of a new drug application or after approval, the drug sponsor submits "the patent number and the expiration date of any patent which claims the drug … or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b), (c)(2); *see also* 21 C.F.R. § 314.53.

C. Generic drugs

54. The FDCA includes an abbreviated process for "generic" drugs. It permits generic drug manufacturers to file an "abbreviated application for the approval of a new drug" (ANDA). 21 U.S.C. § 355(j)

55. A generic drug manufacturer seeking approval of an ANDA must demonstrate that its product is bioequivalent to a drug that FDA has previously approved. 21 U.S.C. § 255(j)(2)(A)(iv).

56. By allowing generics to shortcut the regulatory process and skip the development process entirely, the FDCA permits "generic drugs [to] piggyback off a previously-approved brand-named drug." *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 703 n.20 (3d Cir. 2016).

57. To protect a brand manufacturer's innovation, hard work, and investment, the FDCA ensured that ANDA applicants could not circumvent a brand manufacturer's patent rights. Instead, an ANDA applicant must certify "with respect to each patent which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval" that "such patent information has not been filed," "such patent has expired," "the date on which such patent will expire," or "that such patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(vii).

58. If a generic manufacturer wishes to apply for approval for only a subset of the approved uses or indications of an approved drug, the application must include "a statement that [any] method of use patent" relating to the approved drug "does not claim such a use." 21 U.S.C. § 355(j)(viii). This process allows generics to use what is commonly called a "Section 8 carve-out" or "skinny label."

D. Teva's ANDA for generic tasimelteon

59. According to FDA, Teva filed ANDA No. 211601 on January 31, 2018, to obtain approval to manufacture and sell a generic version of HETLIOZ® (Teva's ANDA product). *See* Exhibit 2 (Teva tentative approval letter); Exhibit 3 (Teva final approval letter).

60. Although Vanda's HETLIOZ® is FDA-approved to treat Non-24 and nighttime sleep disturbances in SMS in patients 16 years of age and older, Teva's ANDA sought approval to market Teva's ANDA product solely to treat Non-24.

61. Specifically, in its September 21, 2021 tentative approval letter, FDA noted that Teva's application contained a statement that a variety of Vanda's patents relating to SMS, including U.S. Patent Nos. 10,179,119, 11,266,622, 9,539,234, 9,730,910, 10,149,829, 10,475,487, 10,610,511, 11,141,400, 10,610,510, 10,980,770, and 11,285,129, "do not claim any indications or other conditions for use for which [Teva] [was] seeking approval." Exhibit 2 (Tentative Approval Letter) at 2-3. That is, Teva represented to FDA that these patents did not

preclude approval of its ANDA because Teva was not seeking approval to market its ANDA products to patients with SMS.

62. Consistent with Teva's carve-out of an SMS indication, the label that Teva proposed and FDA eventually approved did not include an SMS indication. Exhibit 4 (Teva proposed/final label).

63. Specifically, Teva's proposed label lists only "Non-24-Hour Sleep-Wake Disorder (Non-24 in adults)" as an approved indication. Exhibit 4 (Teva proposed/final label) at 1.

64. Teva's proposed label contains dosage and administration instruction only for "Non-24" in adults. Exhibit 4 (Teva proposed/final label) at 1.

65. In the more detailed "Indications and Usage" section of the Teva's proposed label, the document states that "Tasimelteon capsules are indicated for the treatment of Non-24 in adults." Exhibit 4 (Teva proposed/final label) at 2.

66. FDA granted final approval of Teva's ANDA on December 12, 2022. Exhibit 3 (Teva final approval letter).

67. In its final approval letter, FDA likewise noted that a variety of Vanda's patents relating to SMS—including U.S. Patent Nos. 10,179,119, 11,266,622, 9,539,234, 9,730,910, 10,149,829, 10,475,487, 10,610,511, 11,141,400, 10,610,510, 10,980,770, and 11,285,129, "do not claim any indications or other conditions for use for which [Teva] [was] seeking approval." Exhibit 3 (Teva final approval letter) at 2-3.

68. Further, consistent with the FDCA, Vanda enjoys a period of orphan drug exclusivity with respect to the SMS indication. *See* 21 U.S.C. § 316.31(a). Vanda maintains exclusivity with respect to the SMS indication until at least December 1, 2027.

69. Consistent with Teva's carve-out of an SMS indication, Teva's FDA-approved final label includes only the indication of Non-24 and not an indication for nighttime sleep disturbances in SMS.

70. Specifically, Teva's FDA-approved final label lists only "Non-24-Hour Sleep-Wake Disorder (Non-24 in adults)" as an approved indication. Exhibit 5 (Teva DailyMed label) at 1.

71. Teva's FDA-approved final label contains dosage and administration instruction only for "Non-24" in adults. Exhibit 5 (Teva DailyMed label) at 1.

72. In the more detailed "Indications and Usage" section of the FDA-approved label for Teva's ANDA product, the label states that "Tasimelteon capsules are indicated for the treatment of Non-24 in adults." Exhibit 5 (Teva DailyMed label) at 2.

E. Teva's false and misleading advertisements and representations

73. On or about December 29, 2022, Teva "launched" its ANDA product at-risk and, in the days following, began publicly marketing and advertising its product as a generic alternative to Vanda's HETLIOZ®.

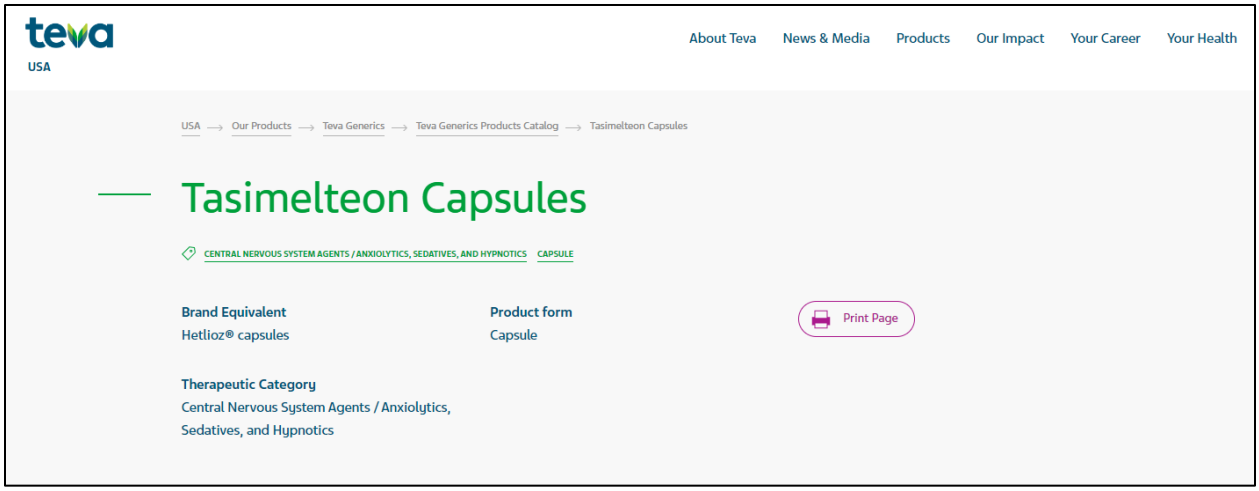
74. Since launching its ANDA product on or around December 29, 2022, Teva has engaged in materially false and misleading advertising of its ANDA Product.

1. False and misleading online catalog marketing

75. Teva owns and operates the website tevausa.com.

76. On tevausa.com, Teva publishes the "Teva Generics Products Catalog."

77. Within the "Teva Generics Products Catalog" appears a webpage entitled "Tasimelteon Capsules":



See Exhibit 6 (*Tasimelteon Capsules*, Teva USA (as of Jan. 12, 2023), perma.cc/Z8F6-6UEZ, https://www.tevausa.com/our-products/tevagenerics/teva-generics-catalog/vision-product-page/tasimelteoncapsules).

78. Teva's Tasimelteon Capsules page provides a false or misleading description of fact or false or misleading representation of fact in at least two ways.

79. *First*, the Teva Tasimelteon Capsules page represents that Teva's ANDA product is a "brand equivalent" to Vanda's HETLIOZ® capsules.

80. This statement is literally false because Teva's ANDA product is approved only for the indication of Non-24, but HETLIOZ® is FDA-approved to treat both Non-24 and nighttime sleep disturbances in SMS.

81. This statement is misleading because a reasonable consumer would understand "brand equivalent" to mean that HETLIOZ® and Teva's ANDA product are always interchangeable when they are not. In particular, FDA has not approved Teva's ANDA product to treat nighttime sleep disturbances in SMS, while HETLIOZ® *is* FDA approved to treat nighttime sleep disturbances in SMS.

82. *Second*, the Teva Tasimelteon Capsules page represents that Teva's ANDA product is an "anxiolytic[]," "sedative[]," or "hypnotic[]".

83. FDA has not approved HETLIOZ® as an anxiolytic, sedative, or hypnotic—and certainly has not done so for Teva's ANDA product.

84. The FDA-approved label for HETLIOZ® does not indicate that HETLIOZ® is an anxiolytic, sedative, or a hypnotic.

85. The final label for Teva's ANDA product, which is materially similar to Vanda's (as the FDCA requires) likewise does not state that tasimelteon is an anxiolytic, sedative, or hypnotic. Exhibit 5 (Teva DailyMed label).

86. Consistent with its FDA-approved label, Vanda's public-facing materials do not indicate that HETLIOZ® is an anxiolytic, sedative, or hypnotic. *See* Vanda, *About Hetlioz® (tasimelteon)* (visited Jan. 14, 2023), https://hetlioz.com/abouthetlioz.

87. The FDA requires that generic drug manufacturers fulfill an "ongoing federal duty of 'sameness.'" *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011).

88. Nonetheless, Teva is promoting its ANDA product as an anxiolytic, sedative, or hypnotic.

89. And Teva is doing so while at the same including a statement that it has an "FDA approval letter."

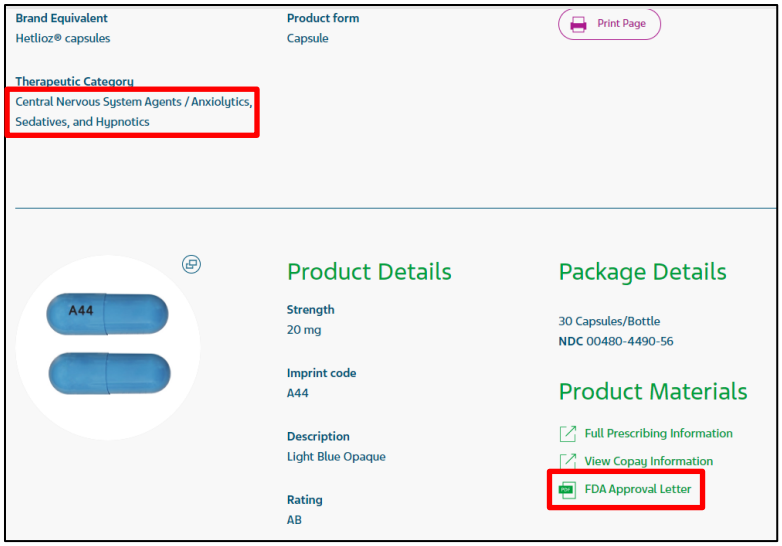


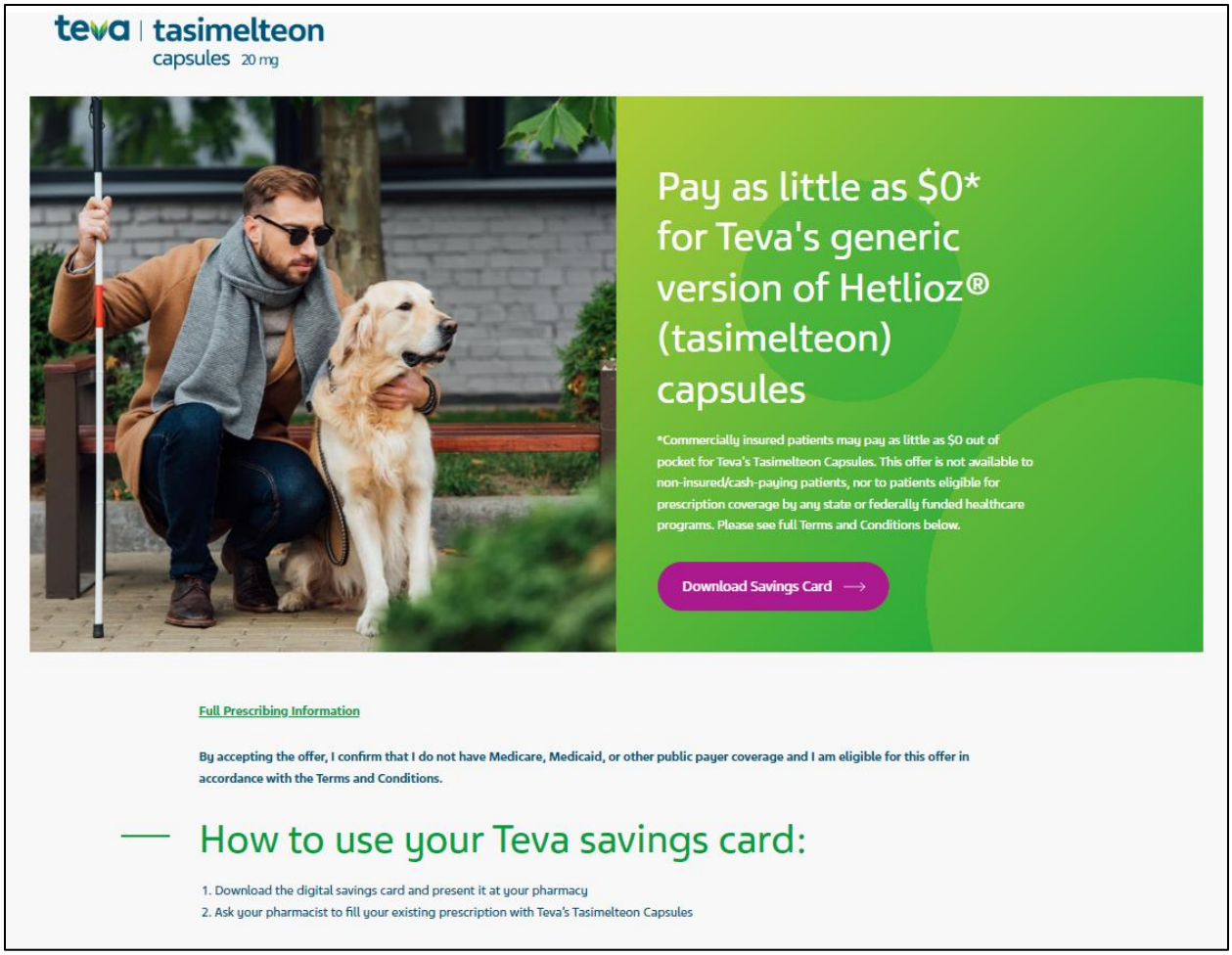
Exhibit 6 (Teva Tasimelteon Capsules).

90. Teva's statement that its ANDA product is an "anxiolytic,' "hypnotic" or "sedative" is misleading because a reasonable consumer would understand it and its context to mean that Teva's ANDA product is an anxiolytic, sedative and/or hypnotic, when FDA has not approved Teva's tasimelteon capsules for such a use. Instead, FDA has only approved Teva's tasimelteon capsules for use in treating Non-24.

91. Teva worsens that impression by including the statement "FDA Approval Letter," which suggests that FDA *has* approved Teva's tasimelteon capsules for use as an "anxiolytic," "hypnotic," or sedative," when it has not. Instead, FDA has only approved Teva's tasimelteon capsules for use in treating Non-24.

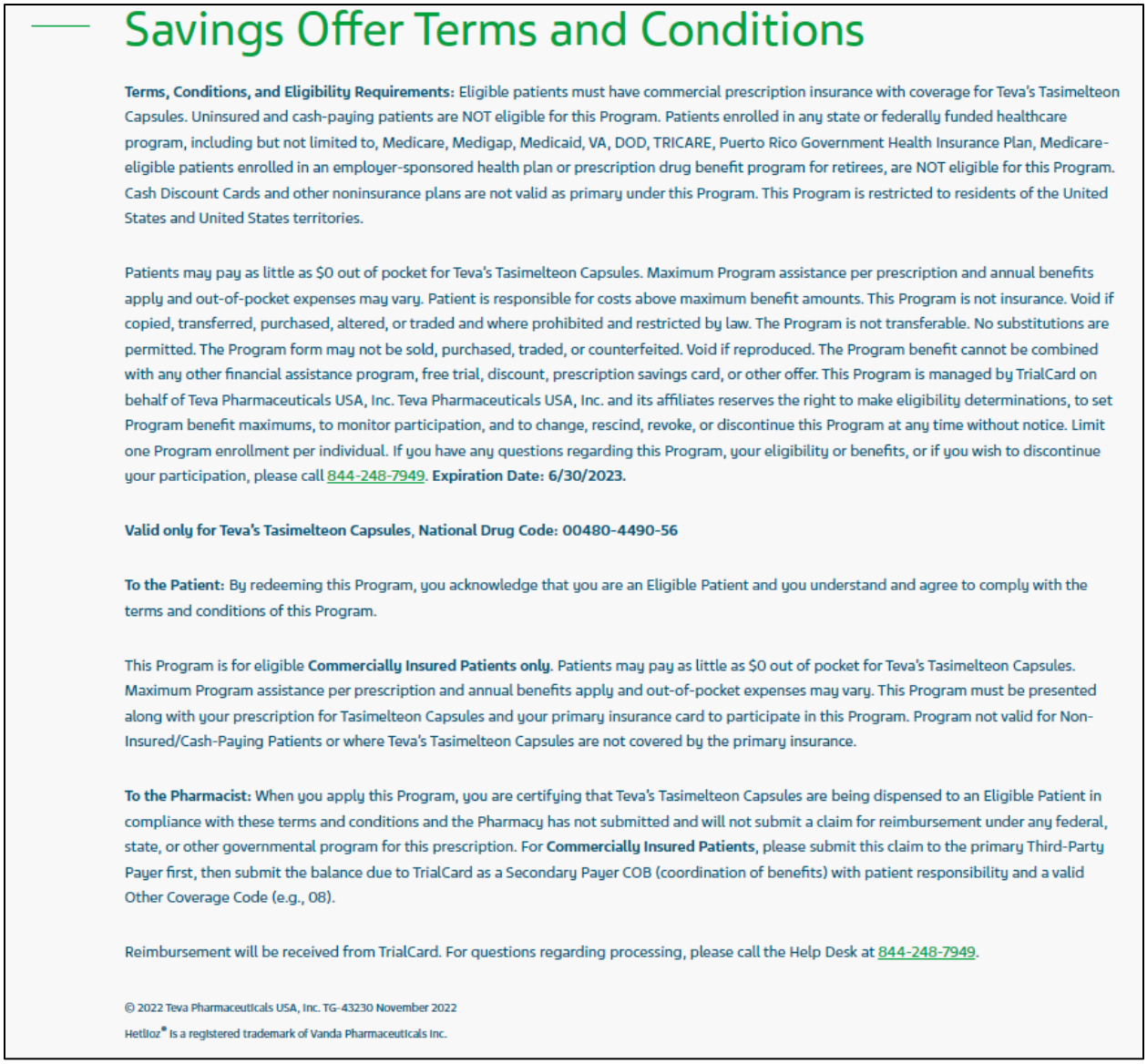
2. False and misleading copay-assistance marketing

92. Teva's website, tevausa.com, markets a "Teva savings card" for its ANDA product through which Teva advertises that patients can pay $0 out of pocket for Teva's ANDA product:



See Exhibit 7 (*Pay as little as $0* for Teva's generic version of Hetlioz® (tasimelteon) capsules*, Teva USA (as of Jan. 13, 2023), perma.cc/M2DY-FY3Y; https://www.tevausa.com/our-products/tevagenerics/tasimelteon-capsules-copay-card).

93. Teva's "savings card" also comes with specific "terms and conditions" that Teva publishes on its website:



Savings Offer Terms and Conditions

Terms, Conditions, and Eligibility Requirements: Eligible patients must have commercial prescription insurance with coverage for Teva's Tasimelteon Capsules. Uninsured and cash-paying patients are NOT eligible for this Program. Patients enrolled in any state or federally funded healthcare program, including but not limited to, Medicare, Medigap, Medicaid, VA, DOD, TRICARE, Puerto Rico Government Health Insurance Plan, Medicare-eligible patients enrolled in an employer-sponsored health plan or prescription drug benefit program for retirees, are NOT eligible for this Program. Cash Discount Cards and other noninsurance plans are not valid as primary under this Program. This Program is restricted to residents of the United States and United States territories.

Patients may pay as little as $0 out of pocket for Teva's Tasimelteon Capsules. Maximum Program assistance per prescription and annual benefits apply and out-of-pocket expenses may vary. Patient is responsible for costs above maximum benefit amounts. This Program is not insurance. Void if copied, transferred, purchased, altered, or traded and where prohibited and restricted by law. The Program is not transferable. No substitutions are permitted. The Program form may not be sold, purchased, traded, or counterfeited. Void if reproduced. The Program benefit cannot be combined with any other financial assistance program, free trial, discount, prescription savings card, or other offer. This Program is managed by TrialCard on behalf of Teva Pharmaceuticals USA, Inc. Teva Pharmaceuticals USA, Inc. and its affiliates reserves the right to make eligibility determinations, to set Program benefit maximums, to monitor participation, and to change, rescind, revoke, or discontinue this Program at any time without notice. Limit one Program enrollment per individual. If you have any questions regarding this Program, your eligibility or benefits, or if you wish to discontinue your participation, please call 844-248-7949. **Expiration Date: 6/30/2023.**

Valid only for Teva's Tasimelteon Capsules, National Drug Code: 00480-4490-56

To the Patient: By redeeming this Program, you acknowledge that you are an Eligible Patient and you understand and agree to comply with the terms and conditions of this Program.

This Program is for eligible **Commercially Insured Patients only**. Patients may pay as little as $0 out of pocket for Teva's Tasimelteon Capsules. Maximum Program assistance per prescription and annual benefits apply and out-of-pocket expenses may vary. This Program must be presented along with your prescription for Tasimelteon Capsules and your primary insurance card to participate in this Program. Program not valid for Non-Insured/Cash-Paying Patients or where Teva's Tasimelteon Capsules are not covered by the primary insurance.

To the Pharmacist: When you apply this Program, you are certifying that Teva's Tasimelteon Capsules are being dispensed to an Eligible Patient in compliance with these terms and conditions and the Pharmacy has not submitted and will not submit a claim for reimbursement under any federal, state, or other governmental program for this prescription. For **Commercially Insured Patients**, please submit this claim to the primary Third-Party Payer first, then submit the balance due to TrialCard as a Secondary Payer COB (coordination of benefits) with patient responsibility and a valid Other Coverage Code (e.g., 08).

Reimbursement will be received from TrialCard. For questions regarding processing, please call the Help Desk at 844-248-7949.

See id.

94. Teva's marketing for the "savings card" states, without qualification, "Ask your pharmacist to fill your existing prescription with Teva's Tasimelteon Capsules."

95. But Teva's ANDA product is approved for only *one* of the indications that Vanda's HETLIOZ® is approved to treat. Teva's ANDA product is only approved to treat Non-24; it is *not* FDA-approved to treat nighttime sleep disturbances in SMS.

96. There are patients with HETLIOZ® prescriptions who have SMS, but not Non-24.

97. Teva's statement and its context are misleading in that a reasonable consumer would interpret it to mean that any patient with a HETLIOZ® prescription can have their prescription filled with Teva's ANDA product instead.

98. The misleading character of Teva's statement is amplified by the savings card's exclusion of patients on "any state or federally funded healthcare program, including but not limited to, Medicare" and "Medicare-eligible patients enrolled in an employer-sponsored health plan or prescription drug benefit program for retirees."

99. Many patients with Non-24 who have HETLIOZ® prescriptions are blind.

100. Because blindness is a recognized disability, many blind patients will qualify for a federally funded healthcare program.

101. By excluding many blind patients from the target audience for the savings card program, Teva is directing this statement to many patients with SMS—but Teva's ANDA product is not FDA-approved to treat these patients with SMS.

102. Upon information and belief, Teva's marketing materials have included these and other false and misleading statements since the at-risk launch of its ANDA product on or around December 29, 2022.

103. Teva intended that these misrepresentations be relied on by drug wholesalers, distributors, direct purchasers, insurance companies, HMOs, prescription drug plan sponsors, pharmacists, pharmacies, patients, physicians, and others.

104. Teva's misrepresentations have had their intended effect. For example, Optum, a large pharmacy benefit manager, recently announced the availability of Teva's ANDA product. Exhibit 8, *Hetlioz® (Tasimelteon) – First-time generic*, Optum Rx (as of Jan. 14, 2023),

perma.cc/DZW5-TMG7; https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_hetlioz_2023-0104.pdf.

105. Optum explains that Teva has launched a "generic version of Vanda's Hetlioz (tasimelteon capsules)" and that "Hetlioz capsules are approved for the treatment of [Non-24] in adults, and for the treatment of nighttime sleep disturbances in [SMS] in patients 16 years of age or older." *Id.*

106. The Optum notice fails to indicate that Teva's ANDA product is not approved to treat SMS patients. On information and belief, the misleading character of Optum's notice is at least in part due to Teva's advertising materials, including but not limited to its online statements, which falsely or misleadingly suggest that Teva's ANDA product is equivalent to HETLIOZ® when it is not.

107. On information and belief, OptumRx has switched the prescription of at least two patients with SMS from HETLIOZ® to Teva's ANDA product.

108. On information and belief, OptumRx's decision to change these patients' medications from HETLIOZ® to Teva's ANDA product was influenced by Teva's deceptive, false, and misleading advertising materials.

F. The harms from Teva's false and misleading advertising

109. Through these misrepresentations, Teva has successfully diverted sales of tasimelteon from Vanda to Teva since on or around December 29, 2022.

110. This diversion of sales has substantially injured Vanda.

111. HETLIOZ® is one of Vanda's two approved products and accounted for nearly 65% of Vanda's revenue in 2021.

112. In 2021, Hetlioz® net sales reached $173.5 million globally; the vast majority of those sales (over $165 million) are in the United States.

113. Between its initial launch in 2014 and the third quarter of 2022, cumulative net U.S. sales of Hetlioz® totaled approximately $900 million.

114. Patients with SMS make up a significant portion of the total population of patients with HETLIOZ® prescriptions.

115. Because of Teva's unlawful conduct, Vanda has suffered and is likely to suffer substantial damages and irreversible harm to its reputation and goodwill.

CLAIMS FOR RELIEF

COUNT I
False Advertising—Lanham Act § 43(a), 15 U.S.C. § 1125(a)

116. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs as though set forth fully herein.

117. Teva's literally false, deceptive, and misleading advertising violates Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

118. Teva has advertised and promoted Teva's ANDA product in interstate commerce in the United States, by literally false, deceptive, and/or misleading representations of the nature, characteristics, qualities, and equivalencies of Teva's ANDA product.

119. Teva's ANDA product directly competes (and has since its at-risk launch directly competed) with Vanda's HETLIOZ®.

120. Teva's advertising and related representations are material and have deceived and influenced a substantial portion of their intended audience, including drug wholesalers, distributors, direct purchasers, insurance companies, HMOs, prescription drug plan sponsors, pharmacists, pharmacies, patients, physicians, and all those who influence purchases of Teva's ANDA products and HETLIOZ®.

121. Teva's literally false, deceptive, and misleading representations have caused sales of tasimelteon in interstate commerce to be diverted from Vanda directly to Teva.

122. Teva's literally false, deceptive, and misleading representations of fact have caused substantial injury to Vanda, including damage to Vanda's sales and profits, business relationships, and goodwill.

123. Teva's acts were willful, malicious, egregious, and in bad faith.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that the Court:

a. Enter judgment in its favor and against Teva;

a. Enjoin Teva from directly or indirectly falsely advertising or promoting tasimelteon or inducing others to purchase or use tasimelteon in place of or in lieu of Hetlioz®, including under the Lanham Act, 15 U.S.C. § 1116(a);

b. Order Teva to publish appropriate corrective advertisements and statements;

c. Award Vanda compensatory damages in an amount to be determined at trial;

d. Order an accounting and disgorgement of profits received from the sale of Teva's ANDA product;

c. Award Vanda enhanced damages;

d. Award Vanda pre-judgment and post-judgment interest;

e. Award Vanda its costs in bringing this action, including reasonable attorneys' fees and expenses, including but not limited to attorneys' fees available in exceptional cases under the Lanham Act, 15 U.S.C. § 1117; and

g. award Vanda such further and additional relief as this Court deems just and proper.

JURY DEMAND

Vanda demands a trial by jury as to all claims and issues so triable.

Dated: January 29, 2023
Newark, New Jersey

s/ Justin T. Quinn

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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: January 29, 2023
Newark, New Jersey

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